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Six Sigma methodology application in the evaluation of the glucose results (2014-2016) obtained by the participant laboratories of Programa Nacional de Avaliação Externa da Qualidade (PNAEQ)

João Reguengos[1,2], Ana Faria[1], Armandina Miranda[1], Helena Correia[1], Ana Cardoso[1], Susana Silva[1], José Requeijo[2]

[1] Instituto Nacional de Saúde Dr. Ricardo Jorge – Departamento de Epidemiologia – Unidade de Avaliação Externa da Qualidade, Portugal;
[2] Departamento de Engenharia Mecânica e Gestão Industrial, Faculdade de Ciências e Tecnologias, Universidade Nova de Lisboa, Monte da Caparica, Portugal.

Background and Aim

Glucose quantification plays a key role in the Diabetes diagnosis and treatment monitoring. In Portugal diabetes prevalence is increasing and last estimates provide a prevalence of 9,8%[1]. The main objective of this study was to evaluate the Sigma level of the participant laboratories of the Clinical Chemistry program of PNAEQ (2014-2016) regarding the Glucose quantification, through two different approaches: by applying a linear regression model which enables performance evaluation of each laboratory individually over time[2]; and by evaluating the general performance of all laboratories on each sample.

Methods

In the evaluation by laboratory, a linear regression model was applied to the quantitative glucose results of 79 laboratories, which have presented at least 8 results between 2014 and 2016. The laboratories results were compared with the consensus value of the respective sample, calculated through Algorithm A, and the Sigma level was obtained considering the desirable specification of the total allowable error based on biological variation.

In the evaluation per sample, the mean bias of each of the 33 samples was determined and its Normal distribution accessed with the Kolmogorov-Smirnov test. The Box-Cox and Johnson transformations were applied when necessary. The Sigma level was determined considering the bias minimum quality specification based on biological variability.

Results

The mean Sigma level obtained in the approach per laboratory was 1,70 Sigma, ranging between 0,56 and 3,40 Sigma, with 34,2% of the laboratories presenting a Sigma level above 2 Sigma. The mean Sigma level obtained in the approach by sample was 1,63 Sigma, varying between 0,74 and 2,15 Sigma with 15,2% of the samples presenting a Sigma level greater than 2 Sigma.

Evaluation	Per Laboratory	Per Sample
Mean Sigma	1,70	1,63
Minimum	0,56	0,74
Maximum	3,40	2,15
Percentage above 2 Sigma	34,2%	15,2%
Statistics considered	Total Error	Bias
Quality Specification criteria	Desirable	Minimum

Table 1: ***Evaluation summary***

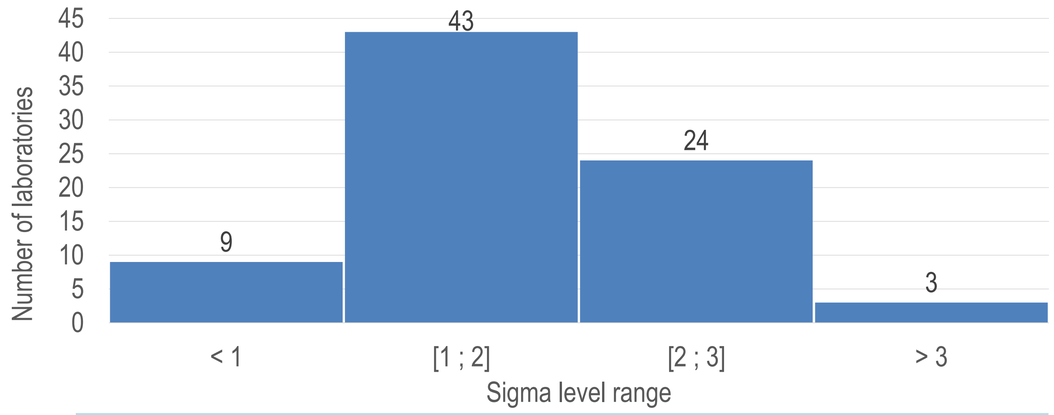

Figure 1: Laboratories Sigma level

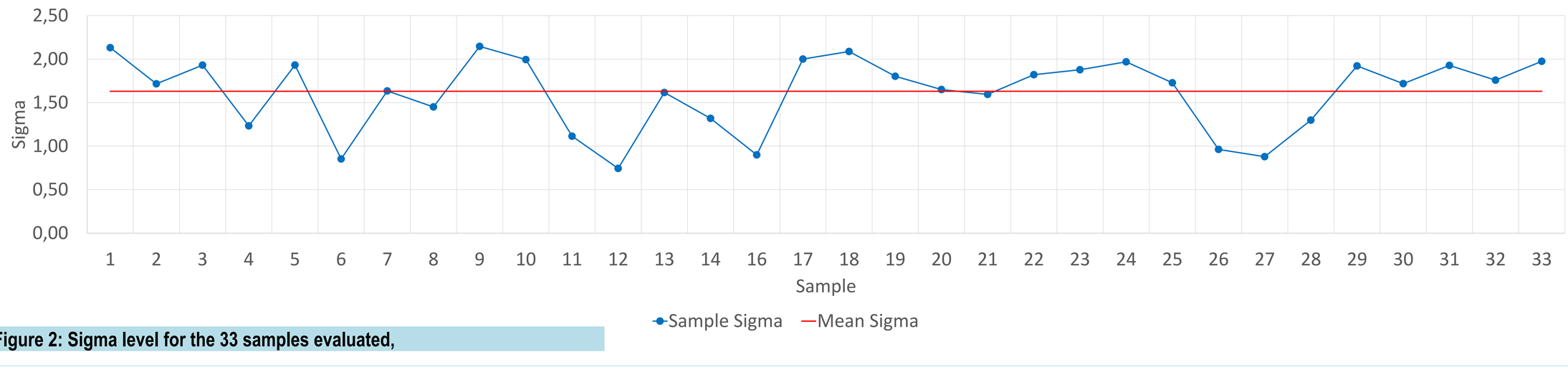

Figure 2: Sigma level for the 33 samples evaluated,

Conclusion

Even though the two approaches are not comparable, the mean Sigma level was similar in both evaluations. The fact that the mean Sigma level is less than 2 Sigma and that only 34,2% of the laboratories presented a Sigma level above 2 Sigma, highlights the need to implement improvement actions. Therefore, it is imperative to identify the causes of results variability in order to develop the right measures to eliminate or reduce the occurrence of errors and improve the harmonization of the laboratories results. This improvement should be accessed with the Sigma metrics, in order to establish a comparison basis with this evaluation. This study corresponds to the Measure phase of the DMAIC (define, measure, analyse, improve and control) cycle, which must be completed in order to accomplish the objectives mentioned before and improve the laboratories performance.

References
[1]Barreto, Marta *et al*, Prevalência, conhecimento e controlo da diabetes em Portugal: resultados do Inquérito Nacional de Saúde com Exame Físico (INSEF 2015), Boletim Epidemiológico Observações. 2017;6(Supl 9):34-8
[2]Meijer P, de Maat MP, Kluft C, et al. Long-term analytical performance of hemostasis field methods as assessed by evaluation of the results of an external quality assessment program for antithrombin. Clin Chem. 2002;48(7):1011

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